Japan 4EE Input to 2nd Stakeholder Consultation – Attachment 4 as draft Appendix on group of substance

Definition of substance grouping should not be defined under RoHS. Definition and judgement relating to chemical substances should be harmonised with those which are internationally recognized or established in EU. More concretely, it should be judged in accordance to the procedure indicated in OECD guidance or ECHA guideline based on the OECD guidance.

Appendix 6 should be replaced to the summary of the ECHA guideline. We prepared following summary based on the discussion in “Small WG”, by which the RoHS officer in the Commission at that time tried to make a “Guidance on definition of a group of similar substances” in 2015. We would like to propose that the summary of ECHA guidance should be attached to the methodology as an Appendix.

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Definition of a group of similar substances based on OECD and ECHA Guidelines

Article 6.1 of the RoHS Directive (2011/65/EU) requires the European Commission to consider reviews and amendments the list of restricted substances in Annex II. The directive gives the possibility to review and assess both single substances as well as groups of similar substances.

The term ‘grouping’ or ‘substances grouping’ here describes the general approach for considering more than one substance at the same time in the assessment. Assessing a group of substances should provide an alternative to the individual assessment of substances, in order to maximise efficiency.

The aim of this document is to provide implementing guidance describing an approach that could be applied in the grouping of substances under RoHS.

1. Grouping of substances under RoHS

Under RoHS, a group of substances subject to assessment for potential restriction of use in EEE should be investigated in accordance with OECD GUIDANCE ON GROUPING OF CHEMICALS, SECOND EDITION (ENV/JM/MONO(2014)4). This OECD Guidance has been incorporated also in "Guidance on information requirements and chemical safety assessment"[1] of ECHA and used in REACH.
As stated in the Guidance, the rationale underpinning the analogue and the category approach may be based on the following:

- Common functional group(s) (e.g., aldehyde, epoxide, ester, specific metal ion);
- A common mode or mechanism of action or adverse outcome pathway
- Common constituents or chemical classes, similar carbon range numbers. This is frequently the case with complex substances16 often known as “substances of unknown or variable composition, complex reaction products or biological material” (UVCB substances);
- The likelihood of common precursors and/or breakdown products via physical or biological processes that result in structurally similar chemicals (e.g., the “metabolic pathway approach” of examining related chemicals such as acid/ester/salt); or

[1] http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf
See R.6.2.1.2 Explanation of relevant concepts (page 69) of ECHA Guidance.
Following information would serve as additional references on this issue:
ECHA “Grouping of substances and read-across” web-site:
http://echa.europa.eu/support/grouping-of-substances-and-read-across
Grouping of substances and read-across approach
Part 1: Introductory note
http://echa.europa.eu/documents/10162/13628/read_across_introductory_note_en.pdf

- An incremental and constant change across the category (e.g., a chain-length category), often observed in physical chemical properties, e.g., boiling point range.

The structural criteria in particular should be considered in combination with other criteria, such as those related to the properties, (eco-)toxicological effects, behaviour or common mode of action of the grouped substances. Indeed, groups of substances should be selected based on the hypothesis that structural changes across the group will produce changes that would affect the whole spectrum of properties in a consistent and coherent trends.
[Note: According to the OECD Guidance, "common mode of action" is one of important factor in deciding what chemicals would not be expected to be members of a category.]

Before a group of similar substances can be assessed for potential restriction under RoHS the following needs to be ensured and documented:

- All members of the group are as far as possible, properly identified by an EC name and number, CAS name or number, and/or one or more equivalent identifiers;
- All criteria are considered, described, and fully documented, including any assumption and/or information used to fill information gaps, as relevant;
- The data and information used for each criteria fulfils the quantity and quality criteria as described in separate RoHS implementation guidance;
- Deviations from the recommended methodology are identified and justified so as to demonstrate equivalent robustness and quality;
- The applicability domain of the group is clearly defined (i.e. minimum similarity requirements, to set the boundaries that are used as inclusion/exclusion criteria) and justified, to allow substances to be considered as members of the group and subject to the decision made on that group under RoHS, after the group has been defined; and
- The benefits of performing the assessment on the group of substances outweigh those of performing the assessment on the substances individually, and this is clearly justified.

No matter the criteria driving the composition of the group, for every group the common elements need to be clearly described and documented, together with the differences that may occur. Among these differences, the following may occur:

- An effect which varies in intensity across the group, such that some members of the group meet the criteria for one hazard classification for the particular endpoint, whereas other members of the group meet the criteria for another;
- The presence of a breakpoint indicating a change in the mode of action or the effect of a consistent tendency across the group, e.g. a peak in activity or a breakpoint in a trend; and/or
- A trend analysis that may apply to a subgroup, but not to the whole group.

When differences between the members of the group exist so that the degree of similarity or commonality is challenged or appears less evident, such differences must be clearly described and categorised as "allowed" (when the difference does not dismiss the commonality for that criteria) or "not allowed" (when the difference dismisses the commonality for that criteria).

Ultimately, decisions on whether to consider substances separately or as a group must be made on a case by case basis. It will be necessary to consider whether the members of a group are sufficiently similar, to determine if it will be simpler to assess these as a group or separately. If the members of a group of substances have little similarity or commonality, the group approach would not be validated (or worthwhile) and instead, a substance-specific assessment would be required and be simpler to carry out.

In practice it may be possible to identify the trends and changes for some but not all of the properties of potential interest in a given group. Likewise, significant differences in structure or composition, leading to significant changes in properties, inconsistent or incoherent trends, and/or different classifications,

indicate that the grouped approach is unlikely to be robust and efficient enough and that a substance-specific assessment is required instead.

Ideally, the robustness and validity of a group of substances should be confirmed or refuted as early as possible in the grouping exercise, in order to avoid an inefficient subsequent assessment and (non-)restriction decision.

2. Boundaries and conditions for success of group of substances

Defining a given group is the result of an iterative process, subject to adjustment as more information becomes available, during e.g. the assessment of the group, or when additional substances potentially eligible for inclusion in the group are identified after the assessment. Subsequent assessments of additional members of a group (including potential substitutes to hazardous substances present in EEE meeting the group's criteria) should be possible at any time, but considering that they require additional dedicated assessments each time, there is an incentive to ensure that as many potential members of a group are included upfront for assessment.

Those defining and assessing a group should be free to further divide or otherwise adjust the composition of the group during the assessment, in order to adapt it to the needs of the assessment as such. They are furthermore recommended to consult the users of such substances and other relevant stakeholders, in order to gather as much information as possible on the various criteria relevant for the group, and to refine as best as possible the scope of the group.

Where one or more additional substances are identified after an assessment has been performed, expert judgement should be used in deciding whether, according to the grouping criteria listed above and applicable to that group, such a substance:

- should be included in the group, and hence make the conclusions of the assessment of the group applicable to that substance; or
- should not be included in the group, in which case the substance would need to be assessed separately instead.

If a substance is considered for inclusion in an existing group, it will be necessary to evaluate both the data for this substance in the light of the group assessment, as well as the group assessment in the light of the data for the additional substance. If the initial group assessment is sufficiently robust, the additional data is unlikely to alter the conclusions of the initial assessment significantly.

The successful use of a group approach should lead to the identification and characterisation (qualitative or quantitative) of the negative impacts that must be tackled by a restriction under RoHS for each and all the members of the group. After a group assessment is performed, the (non-)restriction decision should enable both to add the group of substances or individual members of that group into Annex II of RoHS.

3. Sources

- RoHS: Articles 6 and 6.1;
- REACH: Section 1.5 of Annex XI;
- ECHA: Pages 65-71 of the ECHA Guidance on information requirements and substance safety assessment (Chapter R.6: QSARs and grouping of substances) (May 2008); and
- OECD: Pages 11-25 of the OECD Guidance on grouping of chemicals (Second edition, April 2014).